Puget Sound Blood Center
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June 30, 2000

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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1601
Rockville, MD 20857

Re: Docket Numbers 92N-0297 and 88N-0258

The Puget Sound Blood Center appreciates the opportunity of offering comments on the final rule concerning the Prescription Drug Marketing Act of 1987 and Prescription Drug Amendments of 1992.

The Puget Sound Blood Center is a non-profit community blood center that supplies all the blood components needed by hospitals and patients in 14 counties in Western Washington. In addition to providing blood components to hospitals, it is the transfusion service for hospitals in the Seattle area. In that capacity it provides compatibility testing, special blood component processing and certain blood derivatives, such as clotting factor concentrates and immunoglobulin preparations to the hospitals for particular patients in the hospital who require transfusion. The Blood Center, in response to community needs also provides a number of health care services directly to patients: the regional comprehensive hemophilia treatment center for patients in Washington, therapeutic apheresis phlebotomy programs and an outpatient transfusion service.

The Blood Center has provided blood components for people with hemophilia in the State since the cryoprecipitate process was developed in the mid-1960's. In 1974 it began one of the first comprehensive regional hemophilia treatment centers, a center which is now affiliated with the federally-funded HTC program through a subcontract with the Oregon Health Sciences Center. The hemophilia program provides care for some 900 patients with congenital bleeding disorders in Washington, Northern Idaho & Montana. The Blood Center supplies clotting factor concentrates directly to patients who are on home treatment and, through its transfusion service, sends concentrates to hospitals for inpatients.

Many hemophilia treatment centers in the federal HTC program, administered by the Maternal & Child Health Bureau of HRSA, buy clotting factor concentrates for outpatient use from the manufacturers at the PHS drug discount price and are required to pass on the savings to patients. This program was authorized by the Veterans Health Care Act of 1992. Last year the Blood Center's participation in this HTC 340B program saved our patients and third-party payers including Medicaid and Medicare $7.6 million.

92N-0297 C100

We are concerned that the proposed final rule insofar as it would prohibit blood centers from distributing blood derivatives would have a detrimental impact on hemophilia patients in Washington by interfering with their long established supply of these derivatives and by significantly increasing their costs. It would also appear to conflict with established Federal policy under which the government has determined that it is in the public interest that cost savings realized through the HTC 340B program be passed to consumers.

Through its hemophilia program and the transfusion service, the Blood Center offers to Washington physicians and hospitals consultations with its staff hematologists concerning the diagnosis and management of bleeding disorders. It also maintains small supplies of specialized blood derivatives such as porcine anti-hemophilic factor and activated Factor VII for emergency treatment of patients with coagulation factor inhibitors. Because both congenital clotting disorders and acquired inhibitors are rare, no hospital in our region could justify maintaining an immediately-available emergency supply. If the final rule were to prohibit the Blood Center from distributing these derivatives to hospitals, thus disrupting their established means of access, it is likely that considerable delays would result in instituting effective treatment of patients presenting to the hospitals with serious bleeding emergencies.

The language of the statute does not require that the final rule prohibit a health care entity from being a licensed wholesale drug distributor or from distributing blood derivatives. We understand, on the contrary, that one of the sponsors of the Prescription Drug Marketing Act urged the FDA in a letter to "avoid disrupting the supply of biologics sold as prescription drugs to individuals such as hemophiliacs". In the region the Puget Sound Blood Center serves, an expansion of the final rule beyond the intent of Congress would disrupt the established supply to people with bleeding disorders, would risk delays in emergency treatment of life-threatening bleeding episodes, and could result in patients having to pay much higher prices for already expensive treatment.

We request that FDA modify the final rule to eliminate language that would prohibit full service blood centers, which provide critical health care services such as transfusion services, hemophilia care, therapeutic plasma exchange and stem cell collections, from distributing blood derivative products.

Sincerely,

Richard B. Counts

Richard B. Counts, MD
Executive Director

FEDERAL EXPRESS

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